NAVAL MEDICAL RESEARCH UNIT SAN ANTONIO
Combat Casualty Care Research Department

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Final Report
Phase I
Joint Operational Evaluation of Field Tourniquets

LCDR Anne L. McKeague, MSC, USN, Ph.D.
Duane Cox
Naval Medical Research Unit San Antonio
Fort Sam Houston, Texas, 78234

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Reviewed:

CAPT Steven Sidoff, USN
Science Review Board Chair
Naval Medical Research Unit San Antonio
3650 Chambers Pass, BLDG 3610
Fort Sam Houston, TX 78234-6315

1 Feb 2012

Reviewed and Approved:

CAPT Vincent DeNinnocentiis, MSC, USN
Commanding Officer
Naval Medical Research Unit San Antonio
3650 Chambers Pass, BLDG 3610
Fort Sam Houston, TX 78234-6315

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Executive Summary

Introduction: Tourniquets have been used since antiquity to control extremity bleeding, reduce and control blood flow, as well as facilitate limb amputation. Extremity hemorrhage remains one of the most prevalent causes of death on the battlefield (Kelley, 2005). Due to advances in technology and new designs of tourniquets, a method is necessary for the Military to assess the effectiveness and suitability of emerging tourniquet devices for their ability to control extremity hemorrhage, withstand environmental conditions on the battlefield, and compare ease of use from training to actual battlefield application. This effort will assess currently-fielded tourniquets as well as emerging devices.

Methods: Characterize and assess tourniquets in a controlled lab environment utilizing criteria developed at the DoD Tourniquet Summit in 2010. Phase I consisted of two sub phases. Sub phase Ia confirmed that all test and measurement equipment was calibrated, functioning as intended, and that all testers were trained to accurately and effectively apply the tourniquets on the test mannequin platforms. Sub Phase Ib followed with the assessment and data collection of each tourniquet’s performance while utilizing the MATT and HAPMED tourniquet training mannequins. Pressure distribution of each of the devices was also characterized using a pressure sensor matrix system to better understand the type of force the tourniquet applied across the constricted area.

Results: A total of ten different models of tourniquets were submitted for testing and evaluation. Observations of device performance were noted throughout testing highlighting the devices’ ability to perform in a safe, effective, and timely manner. Of the ten, eight devices completed sub phase Ia by meeting or exceeding the set criteria. The TK4 and TK4-L were removed from the study due to mechanical failures and safety concerns. Of the remaining eight tourniquets, two devices did not meet performance standards. The RAMSEY failed to obtain occlusion on 90% of the test performed on mannequin platforms. The SWAT-T tourniquet failed to obtain occlusion on 70% of the test.
performed on mannequin platforms. Application time with this device averaged 149 seconds compared to 35.5 seconds for the remainder of the tourniquet devices under test.

**Conclusions:** Controlled laboratory metrics were used to assess the effectiveness and suitability of emerging tourniquet devices for their ability to control extremity hemorrhage, and to provide a safe, easy, and timely hemorrhage control device. Testing the tourniquet devices in a controlled setting will benefit the selection process by removing variables associated with field testing and provide metrics to give a better understanding of the devices as designed. The results of this study will provide insight on the tourniquets ability to be a safe, effective, and timely hemorrhage control device for the next phase of the study.

1. **INTRODUCTION**

Tourniquets have been used since antiquity to control extremity bleeding, reduce and control blood flow, as well as facilitate limb amputation. Extremity hemorrhage remains one of the most prevalent causes of death on the battlefield (Kelley, 2005). Due to advances in technology and new designs of tourniquets, a method is necessary for the Military to assess the effectiveness and suitability of emerging tourniquet devices for their ability to control extremity hemorrhage, withstand environmental conditions on the battlefield, and compare ease of use from training to actual battlefield application. This effort will assess currently-fielded tourniquets as well as emerging devices.

The Joint Operational Evaluation of Field Tourniquets (JOEFT) will consist of two phases. The first phase (covered under the JOEFT Phase I test plan) will validate the requirements for efficacy, as determined by the March 2010 Tourniquet Working Group. This phase will be conducted in a laboratory setting and will utilize tourniquet training mannequins as the test platform. Tourniquets under evaluation will be determined by Marine Corps Systems Command (MCSC) based on criteria listed within the Request for Information (RFI) (Appendix B). Tourniquets will be down-selected from Phase I if necessary, based on performance and safety, for progression into Phase II. Phase II, will move the selected tourniquet devices into human volunteer testing phase.

Phase I will be broken into two sub-phases. Sub phase Ia will ensure that all test equipment is functioning as intended, and that all testers can accurately and effectively apply the tourniquets on the test mannequin platforms. Device specifications will be noted in the Specification Requirements Data Collection Sheet. Sub phase Ib will include the assessment and data collection of each tourniquet’s performance while under test on the MATT and HAPMED mannequins. Phase I, in its entirety, will be conducted at the Naval Medical Research Unit, San Antonio (NAMRU-SA) facility at Fort Sam Houston, TX.
The goal of this effort is to provide the Services with a detailed analysis of tourniquet baseline data. This information will aid in the comparison of current and future tourniquet devices in support of combat operations.

2. MATERIALS and METHODS

2.1 Test Equipment

Descriptions of equipment items and devices under evaluation are derived from publicly-available manufacturer or distributor sources.

2.1.1 Multiple Amputation Trauma Trainer (MATT)™ Series 1500 Trauma Simulator – TraumaFX™

The TraumaFX™ product line includes an end-state high fidelity lower body, the Multiple Amputation Trauma Trainer (MATT)™, (Figure 1) that can be paired with a matching upper body, other existing training aids, and can be worn by human patient simulators or human actors to support realistic training for hemorrhage control and other critical injuries.

The current upper body components includes realistic skin, with the weight and feel to stimulate that of a human trauma patient, a tension pneumothorax penetrating wound on the chest, and abdominal training elements.

![Figure 1: MATT™ mannequin](image)

2.1.2 Tekscan I-Scan® Pressure Measurement System

I-Scan®, (Figure 2) the user-friendly force and pressure measurement system, displays and records dynamic and static interface pressure distribution data. The system includes Windows-based software, scanning electronics, and sensors.
The scanning electronics rapidly scan and record pressure data from an array of thousands of independent sensing elements contained within each sensor at a rate of up to 2,288,000 sensing elements/second.

Key features include:

- Ultra-thin, durable and reusable pressure sensors
- Sensors with pitch as fine as 0.625 mm (0.025 in.)
- USB connectivity to your computer
- Fast (100 Hz) sensor scanning
- Accurate, repeatable measurements
- Real-time display of pressure sensor data
- Recording and playback of dynamic pressure images
- Graphing and data analysis capabilities
- Easy to set-up and portable

![Figure 2: Tekscan I-Scan®](image)

### 2.1.3 HAPMED Mannequin for Tourniquet Training

The HAPMED mannequin leg (Figure 3) provides stand-alone, hands-on skills training in which trainees can experience the actual torque required to stanch bleeding from an extremity wound and be timed on tourniquet application. Sensors within the leg gauge the amount of pressure being applied, and as the tourniquet is tightened, LED lights on the tourniquet trainer indicate that the bleeding is being slowed by the application of the tourniquet. When the tourniquet is applied, per amount of torque needed on an actual human, the lights indicate that he or she has successfully stopped the bleeding. However, if the tourniquet is loosened, the “bleeding” will begin again. In advance of the trial commencement, the trainee is told that when they think the trial is complete
they should press the “finish” button on the touch screen. Once the finish button has
been pressed, there is a five second time delay to ensure that the tourniquet was
properly secured and didn’t slip if the trial was ended hastily. The after action review
then displays on the touch screen and shows the number of seconds it took to stop the
bleeding, the amount of blood loss, the number of tourniquets placed and if they were
placed in the appropriate locations.

- **Outer skin.** The outer skin is primarily made from silicone with additional agents
  added for realistic feel and a tougher skin that is pliable but also resists tearing.

- **Wound site.** One wound site (an amputation) at the level of the knee cap depicts
  a wound requested to look grisly and gory. Wound depicts bleeding through the use
  of impregnated LED lights.

- **Touch screen control panel.** The touch screen control panel enables stand-alone
  scenario based training with or without an instructor. It intuitively walks both
  trainees and instructors through the trial setup and start processes. The tourniquet
  trainer comes with seven preset scenarios that cover wound and battlefield
  conditions of increasing degrees of difficulty. Each scenario option corresponds to a
  video scenario in the computer-based training module and offers a synopsis of
  tactical field conditions and patient size prior to commencing the trial. Instructors
  can press the “custom” button to set alternate scenarios directly from the
  mannequin leg. Some of the scenarios provide feedback to the trainee as the trial
  progresses. Other more difficult scenarios require the trainee to press the “finish”
  button in order to view the after action review of their performance. See Figure 4.
2.1.4 Nicolet VersaLab SE Doppler Ultrasound System

The Nicolet VersaLab (Figure 5) is a general-purpose portable Doppler ultrasound system used for the evaluation of blood flow in the peripheral vascular system. The unit consists of 4 and/or 8 MHz transducer frequencies optimized for detecting blood flow in various parts of the body.

![Figure 5: Nicolet VersaLab](image)

2.2 EQUIPMENT UNDER TEST (EUT) (in no particular order)

2.2.1 Combat Application Tourniquet® (CAT)

The Combat Application Tourniquet® (CAT) (Patent Pending) (Figure 6) is a small and lightweight one-handed tourniquet that completely occludes arterial blood flow in an extremity. The CAT uses a Self-Adhering Band and a Friction Adaptor Buckle to fit a wide range of extremities combined with a one-handed windlass system. The windlass uses a free moving internal band to provide true circumferential pressure to an extremity. The windlass is then locked in place; this requires only one hand, with the Windlass Clip™. The CAT also has a Hook-and-Loop Windlass Strap™ for further securing of the windlass during patient transport.

![Figure 6: CAT Tourniquet](image)
2.2.2 Special Operations Forces Tactical Tourniquet – Wide (SOFTT-W)

The Special Operations Forces Tactical Tourniquet-Wide (SOFTT-W) (Figure 7) is the result of an exhaustive 24 month research initiative compiling end-user research and laboratory studies to develop a more effective, easier to use tourniquet for all environments. High-strength, lightweight alloy components are used in critical areas of function ensuring reliability in the most challenging of circumstances and on the largest of limbs. With a true 1-1/2” tourniquet strap and a quick-connect buckle that eliminates the need to ever re-thread the strap, application is faster and easier.

Features:
- A true 1 1/2” constricting band for increased constricting pressure and comfort.
- Quick-release, snap-lock buckle design, allowing rapid re-routing of the band around trapped limbs without rethreading
- Lower-profile, lighter weight alloy components, providing the required strength and durability only metal can offer
- Single application method regardless of location
- 25% lighter than the current SOFTT and reduced size for easier storage

![Figure 7: SOFTT-W Tourniquet](image)

2.2.3 Tourni-Kwik 4 (TK-4) Tourniquet

TK-4 (Tourni-Kwik 4) (Figure 8) is a one-handed tourniquet made to stop arterial bleeding quickly and efficiently from combat or accidental amputations. TK-4 features a strong elastic latex band with two steel s-hooks fastened to it, making it easy to use yet durable enough for even the most traumatic injuries. It is developed and engineered specifically for combat self-help: Full one-handed application, quick and direct. Even for the First Responder or Law Enforcement personnel on a mass casualty scene, it allows fast, sure treatment of the injured until help arrives. Tourni-Kwik is packaged in a compact vacuum-sealed poly-plastic bag, ensuring long shelf life and providing small, easy storage, size: 4”x40”, color: Olive drab (OD).
2.2.4 Tourni-Kwik 4 for Legs (TK-4L)

Tourni-Kwik 4L (Figure 9) improves on the design of the TK-4 with a stronger design, for use on wider parts of the body, including leg and arm injuries. For the individual in the front line combat environment, immediate first aid is more than just a necessity, it could mean the difference between life and death. Severe injuries in such inaccessible areas create the need for trauma care which can be administered quickly, easily and effectively.

2.2.5 M2 Ratcheting Medical Tourniquet™ (Combat version)

The Ratcheting Medical Tourniquets™ (RMT™) (Figure 10) control life-threatening extremity bleeding. The only self-locking tourniquet. Compact, lightweight, and rugged. ‘Easily’ applied with one hand. Simple, intuitive ‘glove’ operation Activation requires ‘only’ uni-directional gross motor skills.
2.2.6  M2 Ratcheting Medical Tourniquet™ (Tactical version)

The Ratcheting Medical Tourniquets™ (RMT™) (Figure 11) control life-threatening extremity bleeding. The only self-locking tourniquet. Compact, lightweight, and rugged. ‘Easily’ applied with one hand. Simple, intuitive ‘glove’ operation Activation requires ‘only’ uni-directional gross motor skills

Figure 11: M2 Ratcheting Medical Tourniquet™ (Combat)

2.2.7  Emergency & Military Tourniquet (EMT)

Delfi’s state-of-the-art Emergency & Military Tourniquet (Figure 12) was designed to combine a high level of tourniquet safety with durable portability. In ground-based tactical situations and pre-hospital settings, the tourniquet is used as a life-saving hemorrhage control device.

Based on proven surgical tourniquet designs, the Delfi E.M.T. completely stops blood flow, is fast and simple to self-apply, and requires minimal training.

Figure 12: Emergency & Military Tourniquet (EMT)
2.2.8 Military Emergency Tourniquet (MET)

The professionals at Tier-One Quality Solutions™ (TQS™) understand this reality and have designed the industry’s most reliable tourniquet device, the Military Emergency Tourniquet™ (MET™) (Figure 13).

Successfully tested and evaluated by the U.S. Navy’s Experimental Diving Unit, the MET™ rapidly and reliably provides lifesaving pressure in the event of critical uncontrolled hemorrhage.

![Figure 13: Military Emergency Tourniquet (MET)](image)

2.2.9 Ramsey’s Red-Pull Tourniquet

This is a developmental item that will be tested as such (Figure 14).

![Figure 14: Ramsey’s Red-Pull Tourniquet](image)
2.2.10 SWAT-Tourniquet™

The SWAT-Tourniquet™ (SWAT-T™) (Figure 15) is a durable tourniquet. It has been advanced aged and heat/cold tested. The SWAT-T™ has an extended shelf life to 5 years. The SWAT-Tourniquet™ is a unique and multipurpose dressing. Its name provides a description for usage Stretch, Wrap, and Tuck, but also the communities for whom it was developed - military and civilian Special Weapons and Tactics teams.

Figure 15: SWAT-Tourniquet™
2.3 TEST PROCEDURES

2.3.1 Phase Ia

- Basic assessment of the physical characteristics of the tourniquet devices
- Training to ensuring the test team can accurately place and use the tourniquets.

2.3.1.1 Basic assessment of the physical characteristics of the tourniquet devices.

This information is recorded on Specification Requirements Data Collection Sheet (SRDCS).

- **Food and Drug Administration (FDA) Registration**: Verify and record FDA registration provided from tourniquet manufacture.

- **Width ≥ 1.5 in**: Took measurements of tourniquet from the most narrow portion of the band which will distribute pressure required to control hemorrhage. These measurements were acquired using Starrett Electronic Caliper 798B. The effective width measurement was also acquired. The effective width is the mechanical means of applying pressure to the band or strap.

- **Length ≥ 37.5 in**: This measurement was acquired by laying the tourniquet flat and measuring from end to end. A effective length was also recorded by securing the tourniquet at the outer most length where the tourniquet can be used. The circumference was measured and recorded.

- **Weight <8oz**: Weight was measured on Ohaus AV412NU and Ohaus AV6101NU electronic scales. Weight was recorded as packaged from manufacture. The weight was also recorded of the unpackaged device.

- **Cubic Size ≤ 25.6 in³**: Measurements of the Height, Width, and length of the packaged device was recorded. These measurements produce a cubic footprint but not the actual cubic displacement.

- **Color (subdued)**: Yes/No answer as to whether the unpackaged device was subdued in color or consisted of colors that are non-subdued.

- **Protective Packaging**: Is the device packaged to protect from environmental elements?

- **Tracking/Date of Manufacture Information**: Was there tracking information present? Was the information printed on the device or the packaging?

- **User Instructions Present**: Were there user instructions present? If so, was the information printed on the device or the packaging?

- **Latex-free Components**: Does the manufacture specify the device is Latex Free or not?

- **Material Component Standards**: Is there information available to specify if the device was manufactured using Military Specification Standards?
• Single Patient Use- Does the device information state that the device is intended for single patient use?

2.3.1.2 Training to ensuring the test team can accurately place and use the tourniquets. All test team members received training on proper tourniquet placement of all tourniquets under test by Dr. John Kragh (COL, USA, retired). Each test team member was required to read the manufacturer’s instructions, apply the tourniquet accordingly to the Tourniquet Test Mannequins and achieve vessel occlusion on the mannequins. Dr. Kragh then signed off on each test team member for competency in tourniquet placement and use. Training documentation is on file with NAMRU-SA.

2.3.2 Phase Ib

• Assess the efficacy of the tourniquets under evaluation, as applied to the HAPMED mannequin
• Assess the efficacy of the tourniquets under evaluation, as applied to the MATT™ mannequin
• Assess each tourniquet for safety concerns, whether in design or application
• Measure pressure distribution of applied tourniquet

2.3.2.1 Basic assessment of the efficacy of the tourniquet devices. Application Requirement Data Collection Sheet (ARDCS)

• Application efficacy of manufacturer instructions - Did the tourniquet device apply according to manufacturer’s instructions?
• Number of turns/wraps/ratchets - Indication of the amount of turns on the windlass handle. 180° of windlass rotation counts as 1 turn. Wraps indication shows number of evolutions the device had on the test platform. Ratchets are the count of individual clicks the device made during application.
• Occlusion of Vessel (Visual) - On the HAPMED this was indicated by all LED lights being extinguished. On the MATT mannequin this was indicated by the flow stoppage.
• Occlusion of Vessel (Pressure) - This is an indication presented by the HAPMED mannequin. If pressure is > 175mmHg the indication presents “Good”. If the pressure was < 175mmHg the indicator presented a “Loose” indication. On the MATT mannequin the loss of audible Doppler signal indicates vessel occlusion and a “Good” application.
2.3.2.2 Assess each tourniquet for safety concerns, whether in design or application.

- Is the tourniquet safe during application? Does the design of the tourniquet pose a safety issue where injury may result during the application of the device?
- The tourniquet’s ability to stay secure once applied. The chance of the tourniquet loosening or failing after application could result in a loss of life.
- What is the pressure distribution of the tourniquet after application? Hot spots of high pressure could cause harm to individuals during training or cause unnecessary nerve damage during hemorrhage control.

2.3.2.3 Measure pressure distribution of applied tourniquet. Pressure measurements were performed using the HAPMED platform. The pressure was recorded using the TekScan I-Scan Pressure Measurement System along with the sensor model/map 5101. The 5101 sensor (Figure 16) has a pressure matrix measuring 4.40 inches X 4.40 inches and a sensels pitch of 0.10 inches. The total number of sensels is 1936 and a sensel density of 100.0 sensel per in². During the testing process the sensor was placed on the mannequin and covered with a thin nylon material (Figure 17) to keep the sensor placed as well as to add small amount of protection from damage. Before testing, the sensor was equilibrated and calibrated using TekScan's pneumatic bladder system PB15C. All sensors are calibrated to produce pressure indication in mmHg range of 0 to 1500mmHg.
Figure 16: 5105 Sensor

Figure 17: Sensor placement on HAPMED
3. RESULTS

3.1 Observances

3.1.1 Combat Application Tourniquet C.A.T.

Application: The initial tightening with the pull strap requires the tourniquet to have all slack removed and be very tight on the appendage. If during the application, the windlass is rotated more than four 180° turns, the gap between the friction buckle and base plate is removed and continuing tightening will create skin pinching.

![Figure 18: C.A.T. applied on HAPMED](image1)
![Figure 19: Friction buckle and base plate.](image2)

3.1.2 Special Operations Forces Tactical Tourniquet – Wide (SOFTT-W)

Application: The quick release snap buckle design expedited application to the MATT mannequin.

The windlass design gains considerable torque per 180° revolution. This being said at times occlusion was achieved in mid revolution. Completing the final revolution to secure the windlass was sometimes difficult and returning the windlass in a loosening direction would lose occlusion.

The buckle design allows the torque to be applied without the pinching or causing pressure hot spots.

![Figure 20: SOFTT-W applied on HAPMED](image3)
![Figure 21: SOFTT-W applied on HAPMED](image4)
3.1.3 Tourni-Kwik 4 (TK-4) Tourniquet, Tourni-Kwik 4 for Legs (TK-4L)

**Design:** The "Effective Length" on this device was not acquired due to its elasticity.  
**Application:** Onsite safety required the use of eye protection to be worn while applying the tourniquet. The combination of the elasticity of the tourniquet and its metal hooks provided the potential for personnel injury if the device broke or slipped while under torque.

Initial hook digs into skin during application.

Very difficult to secure or anchor hook after the tourniquet was applied.

Failure: The TK-4L broke during training on the first application. The TK-4 broke during the first test trial on the HAPMED. On both the TK-4 and TK-4L the nylon strap frayed and broke at the connection to the metal hook.

**NOTE:** 21Sep11: With concurrence of MCSC Kevin Joyner, no further testing of the TK-4 and TK-4L tourniquets due to safety concerns and mechanical failures. The user was at risk when applying device due to the elasticity of the tourniquet and its metal hooks creating the potential for injury.

![Figure 22: TK-4 applied on HAPMED](image)

![Figure 23: Noted Catastrophic Failure](image)

![Figure 24: Noted Catastrophic Failure](image)

![Figure 25: Noted Catastrophic Failure](image)
3.1.4 M2 Ratcheting Medical Tourniquet™ (Combat version)

**Application:** Quick and easy tourniquet to apply. Mechanical ratchet provides good resolution on the torque applied. Slight inward pressure required on ratchet while applying to prevent buckle/gear slippage. Slight skin creasing and strap wrinkling noted.

![Figure 26: RMT Combat applied on HAPMED](image)

![Figure 27: Strap wrinkling](image)

3.1.5 M2 Ratcheting Medical Tourniquet™ (Tactical version)

**Application:** Quick and easy tourniquet to apply. Mechanical ratchet provides great resolution on the torque applied. Slight skin creasing and strap wrinkling noted.

![Figure 28: RMT Tactical applied on HAPMED](image)

![Figure 29: Strap wrinkling](image)

3.1.6 Emergency & Military Tourniquet (EMT)

**Design:** Metal clamp is large and heavy. The heaviest tourniquet tested.

**Application:** Quick and easy tourniquet to apply. Pneumatic design proves very reliable and fine resolution on the applied pressure. The wide design creates occlusion at lower pressure.
3.1.7 Military Emergency Tourniquet (MET)

**Design:** Packaging as received for testing required cutting instrument to open. The contents of the packaging included a carrying pouch with instructions and a sharpie.

**Application:** The strap requires steady tension before the initial turning of the windlass and is one of the more difficult windlass tourniquets to apply. An effort must be made to twist the windlass away from the windlass securing strap. If this extra effort is not made, the windlass will not be secured under the first strap and must use the adjustable securing strap.

3.1.8 Ramsey’s -Red-Pull Tourniquet

**Design:** Packaging is not sealed to prevent environmental damage. The color of the tourniquet is not subdued. The tourniquet design is hard to remove strap from buckle making it difficult to apply when you cannot slip the tourniquet up and over the injured limb.

**Application:** *This tourniquet system failed to obtain occlusion in 90% of tests.* The tourniquet buckle design rotates and prevents material from sliding through. Unable to acquire sufficient torque to obtain occlusion.
3.1.9 SWAT-Tourniquet™

**Application:** This tourniquet system is very difficult to apply and obtain occlusion on the tourniquet training devices. *This tourniquet required on the average 149 seconds* to apply. If occlusion was obtained, securing the tourniquet was very difficult and would come unsecured with little effort. *This tourniquet system failed to obtain occlusion for 70% of tests.*
3.2 Data Collection

3.2.1 Basic assessment of the physical characteristics of the tourniquet devices. Chart 1 shows the summary of the individual tourniquet groups taking the average of 5 devices. The entries shown in red fall outside suggested parameters.

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<th>TK-4L</th>
<th>RMT CBT</th>
<th>RMT TAC</th>
<th>EMT</th>
<th>MET</th>
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<td>Yes</td>
<td>No</td>
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Chart 1: Assessment Summary of the Physical Characteristics.

3.2.2 Basic assessment of the efficacy of the tourniquet devices. Chart 2 shows the Application Requirement Data Collection Sheet (ARDCS). This data was acquired during the performance phase. The TK-4 and TK-4L are grayed out in Chart 2, due to the removal of the TK-4 series because of safety concerns during application and the catastrophic failures occurring during the first trials. The Ramsey also had 10% success at obtaining occlusion on the tourniquet test mannequins. The device has a mechanical issue that will not allow the required constriction to be obtained for occlusion. The SWAT-T had 30% success rate at obtaining occlusion but the time required to obtain occlusion averaged 149 seconds as compared to 35.5 seconds for the remainder of the tourniquet devices.
## Chart 2: Assessment Summary of Application Efficacy

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<td>Yes</td>
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3.2.3 Pressure Distribution Comparison. The following graphs show a cross-section representation (Figure 38) of the pressure applied by the tourniquet device. The pressure curve is defined by the mechanical parameters of the device. Width, material and constriction method will determine the pressure uniformity or lack of applied to the limb. The pressure pattern to the limb has shown devices that apply the pressure in a pattern similar to that of a bell curve are able to reach occlusion at lower pressures than devices that have high peaks on the edges and lower pressure towards the center. Examples of the bell curve pressure pattern can be seen if the C.A.T (Graph 1), EMT (Graph 2) and on the MET (Graph 2).

The next set of graphs show devices that divert the pressure mainly on the edges of the device. These devices require higher overall pressure to obtain occlusion. The pressure signature for these devices exhibit steeper edges and lower center pressure. The examples can be seen if the SOFT-W (Graph 4), RMT Combat (Graph 5) and the RMT Tactical (Graph 6).
Graphs of the remaining two devices did not obtain occlusion during the pressure measurements. The pressure signatures cannot be determined due to low pressure applied. The graphs represent SWAT-T (Graph 7) and RAMSEY (Graph 8).
3.2.4 **Tourniquet Resolution**

The mechanical tourniquet devices utilize turns of windlass, ratchets, and pumps to increase applied pressure. The amount of work required to move the tourniquet from one pressure level to the next is based on the type of mechanical advantage the device provides. The windlass types of tourniquets tested create torque by twisting a strap making the tourniquet constrict. The size of the strap is directly proportional to the amount of work required. As straps are twisted the twist gets larger and mechanical advantage is decreased. This being said, as the constriction increases the amount of work required increases. The ratcheting type of tourniquet use levers and gears to provide the mechanical advantage. The finer the gear steps the more resolution the tourniquet has and the easier it is to move from one pressure level to the next. The pneumatic style tourniquet increases its pressure by increasing air pressure inside a bladder. The bladder area size determines the total amount of force applied and the work required depends on the amount of air added per pump. The smaller the pump action the better the tourniquet resolution.

The importance of resolution. It is given, the finer the resolution the easier the tourniquet is to apply. The key to the having better resolution lies in the amount of pressure control the user has with each tourniquet. By design, the tourniquet device can have from fine to course pressure control (Graph 9). The windlass tourniquets tested increase pressure on average of 58mmHg per revolution (Figure 39), the ratchet types increase an average of 22mmHg per ratchet (Figure 40). The pneumatic types are able to increase the pressure from 1 to 6mmHg depending on the amount the bulb is squeezed (Figure 41). The ability of controlling the applied pressure will increase the safety of these devices and the ability to obtain occlusion with the minimum required pressure.

![Graph 9: Represents the pressure increase per unit of work.](image_url)
Figure 39: Shows the pressure increase of the windlass types of tourniquets. The average pressure step size for the C.A.T. is 63mmHg and for the MET it is 53mmHg.

Figure 40: Shows the pressure increase of the ratchet types of tourniquets. The average pressure step size for the RMT Combat is 25mmHg and for the RMT Tactical it is 19mmHg.
Figure 41: Shows the pressure increase of the pneumatic type of tourniquets. The average pressure step size for the EMT is 6mmHg. Also noted is the curve shape. The step sizes decrease as pressure increases.

4. CONCLUSIONS

The objective of this test was to provide the Services with a detailed analysis of tourniquet baseline data according to the consensus criteria generated at the 2010 DoD Tourniquet Summit. The information provided in this report will aid in the comparison of current and future tourniquet devices to support combat operations. This report also aids the government test sponsor a means to evaluate whether or not a tourniquet meets consensus criteria and if its use provides practical application or safety concerns.

Controlled laboratory metrics were used to assess the effectiveness and suitability of emerging tourniquet devices for their ability to control extremity hemorrhage, as well as provide a safe, easy, and timely hemorrhage control device. This evaluation process, which started in the controlled lab setting, will have to migrate from a lab environment into the hands of a user before the testing process can be completed. Use of the data acquired in this study will benefit the selection process by removing the variables associated with field testing and by providing a controlled environment to equally compare all devices. The results of this study will provide a metric on the tourniquets ability to be a safe, effective, and timely hemorrhage control device for the phase II Testing by Users.

Pressure data collected will give insight on the tourniquet’s ability to efficiently distribute pressure and avoid high pressure points which could cause damage or pain while the tourniquets are applied to human subjects in Phase II.
5. Acknowledgment - Disclaimer

This work was supported by MARCORSYSCOM (Marine Corps Systems Command) and the United States Army Medical Material and Development Agency (USAMMDA). The views expressed herein are those of the authors and do not necessarily reflect the official policy or position of the Departments of the Navy or Defense, nor the US Government. The use of commercially available products does not imply endorsement. I am a military service member (or employee of the U.S. Government). This work was prepared as part of my official duties. Title 17 U.S.C. §105 provides that ‘Copyright protection under this title is not available for any work of the United States Government.’ Title 17 U.S.C. §101 defines a U.S. Government work as a work prepared by a military service member or employee of the U.S. Government as part of that person’s official duties.
Appendix A: Pressure Analysis

A.1 C.A.T.

Figure A01: Tekscan Pressure Sensor data analysis for the C.A.T. showing three replications as applied on the HAPMED Leg Training Device. Pressure vs. Time plots show pressure increase during application of the tourniquet. Pressure vs. Relative Distance shows pressure distribution across the band of the tourniquet. The lower Contour Plots provide a 3D representation of the pressure applied by the tourniquet device. Note: pressure represented by the yellow, orange and red shows pressure > 1000mmHg. Most instances this occurred in areas where the mannequin skin is crimped or pinched.
A.2 SOFT-T

Figure A02: Tekscan Pressure Sensor data analysis for the SOFT-T showing three replications as applied on the HAPMED Leg Training Device. Pressure vs. Time plots show pressure increase during application of the tourniquet. Pressure vs. Relative Distance shows pressure distribution across the band of the tourniquet. The lower Contour Plots provides a 3D representation of the pressure applied by the tourniquet device. Note: pressure represented by the yellow, orange and red shows pressure > 1000mmHg. Most instances this occurred in areas where the mannequin skin is crimped or pinched.
A.3 RMT Combat

Figure B03: Tekscan Pressure Sensor data analysis for the RMT Combat showing three replications as applied on the HAPMED Leg Training Device. Pressure vs. Time plots show pressure increase during application of the tourniquet. Pressure vs. Relative Distance shows pressure distribution across the band of the tourniquet. The lower Contour Plots provides a 3D representation of the pressure applied by the tourniquet device. Note: pressure represented by the yellow, orange and red shows pressure > 1000mmHg. Most instances this occurred in areas where the mannequin skin is crimped or pinched.
A.4 RMT Tactical

Figure A04: Tekscan Pressure Sensor data analysis for the RMT Tactical showing three replications as applied on the HAPMED Leg Training Device. Pressure vs. Time plots show pressure increase during application of the tourniquet. Pressure vs. Relative Distance shows pressure distribution across the band of the tourniquet. The lower Contour Plots provides a 3D representation of the pressure applied by the tourniquet device. Note: pressure represented by the yellow, orange and red shows pressure > 1000mmHg. Most instances this occurred in areas where the mannequin skin is crimped or pinched.
Figure A05: Tekscan Pressure Sensor data analysis for the EMT showing three replications as applied on the HAPMED Leg Training Device. Pressure vs. Time plots show pressure increase during application of the tourniquet. Pressure vs. Relative Distance shows pressure distribution across the band of the tourniquet. The lower Contour Plots provides a 3D representation of the pressure applied by the tourniquet device.
Figure A06: Tekscan Pressure Sensor data analysis for the MET showing three replications as applied on the HAPMED Leg Training Device. Pressure vs. Time plots show pressure increase during application of the tourniquet. Pressure vs. Relative Distance shows pressure distribution across the band of the tourniquet. The lower Contour Plots provides a 3D representation of the pressure applied by the tourniquet device. Note: pressure represented by the yellow, orange and red shows pressure > 1000mmHg. Most instances this occurred in areas where the mannequin skin is crimped or pinched.
Figure A07: Tekscan Pressure Sensor data analysis for the RAMSEY showing three replications as applied on the HAPMED Leg Training Device. Pressure vs. Time plots show pressure increase during application of the tourniquet. Pressure vs. Relative Distance shows pressure distribution across the band of the tourniquet. The lower Contour Plots provides a 3D representation of the pressure applied by the tourniquet device. Note: The three applications shown did not obtain occlusion by reaching minimum 175mmhg.
A.8 SWAT-T

Figure A08: Tekscan Pressure Sensor data analysis for the MET showing three replications as applied on the HAPMED Leg Training Device. Pressure vs. Time plots show pressure increase during application of the tourniquet. Pressure vs. Relative Distance shows pressure distribution across the band of the tourniquet. The lower Contour Plots provides a 3D representation of the pressure applied by the tourniquet device. Note: TQ48 shown in the first series did not obtain occlusion.
APPENDIX B

Solicitation Number: M6785411I3039
Notice Type: Sources Sought
Synopsis:
Added: May 04, 2011 2:26 pm

Marine Corps Systems Command (MARCORSYSCOM), Family of Field Medical Equipment (FFME), in coordination with the U. S. Army Medical Materiel Development Activity (USAMMDA), wishes to validate a new test protocol developed during the Department of Defense tourniquet working group (DOD TWG) meeting held in March, 2010. The participants of the meeting are also interested in testing pre-hospital/field tourniquets currently in use by the Services, as well as, other applicable designs currently available on the market.

The current test protocol being finalized will be accomplished in two phases. The first phase will be conducted using a mannequin and will validate the research protocol developed during the DOD TWG as well as identify any tourniquets that are not suitable for moving into phase two.

The second phase will evaluate pre-hospital/field tourniquets meeting the requirements listed within this RFI and that have successfully completed phase one. Though all companies are welcomed to forward all concepts, MARCORSYSCOM retains the right to withdraw any products based on the advice of participating SMEs, due to safety concerns or any other reason. The pre-hospital/field tourniquets shall meet the following requirements to be considered: (1) Must occlude arterial blood flow to upper and lower extremities; (2) Minimum width must be 1.5 in; (3) Weight must not exceed 8oz; (4) Color must be subdued; (5) Device must be compact; cube must not exceed 6.5 in x 1.75 in x 2.25 in; (6) Device must have a protective casing; this enclosure must be sealed or shrink-wrapped; (7) Device must be easy to open in an operational environment; (8) Minimum length must meet or exceed 37.5 in; (9) Product must be registered appropriately with the FDA.

The following characteristics are desired, but are not required in the case of the pre-hospital/field tourniquets: (1) Capable of self-application; (2) Possess tracking information; quality assurance or date of manufacture present on device; (3) Capable of storage temperatures between -60 F to +150 F without affecting performance; (4) Capable of operational temperatures between -60 F to +130 F without affecting performance; (5) Device will not break or deform with applied pressure of 0-500 mmHg; (6) Use in arctic, desert, tropical, and temperate environments without affecting performance; (7) Use with UV exposure will not affect performance; (8) Capable of being used while wearing full kit gear, in low light and no light; (9) Use with gloves: flight gloves, MOPP gloves, shooting gloves, and cold weather gloves without affecting performance; (10) Latex-free; (11) Single patient use; capable of repositioning from over clothing to skin on same patient; (12) Instructions for use will be inside the package or will appear on the device in a written or pictorial format; (13) User will be able to correctly apply the device following instructions included in packaging; (14) Stitching and other connective methods will be sufficient for pressures exerted on materials according to device requirements. Interested firms are requested to provide 10 to 15 tourniquets by 3:00 PM Local Time, 07 June 2011 for test and evaluation.

The tourniquets must be submitted to the following address: Marine Corps Systems Command, 50 Tech Parkway, Suite 301, Attn: Kevin Joyner Stafford, VA 22556. For information about Family of Field Medical Equipment systems, see the MARCORSYSCOM website at http://www.marcorsycom.usmc.mil/sites/cse/.

Interested firms should submit capabilities and experience descriptions, design approaches, design concepts, and any other relevant information to MARCORSYSCOM. Firms should also submit business size information. This information shall be submitted no later than 3:00 PM Local Time, 07 June 2011 to Marine Corps Systems Command, ATTN: Mark Sanderson, CESS, CT023, 2200 Lester Street, Quantico, VA 22134. This
information may also be submitted electronically to mark.sanderson@usmc.mil.

Submitted tourniquets and information will not be returned. All data received in response to this announcement marked or designated as corporate or proprietary information will be protected from release outside the Government in accordance with the provisions of the Freedom of Information Act and Privacy Act. This is a request for informational purposes only. This is not a Request for Proposal (RFP), Invitation for Bid (IFB), Request for Quotation (RFQ), or an announcement of a solicitation. No solicitation document exists. The submission of this information is for planning purposes only, and is not to be construed as a commitment by the Government to procure these items, nor does the Marine Corps intend to award based on this sources sought/market research, or otherwise pay for the information requested.

No entitlement for the payment of direct or indirect costs or charges by the Government will arise as a result of submission of responses to this RFI and Government use of such information.

Contracting Office Address: ATTN: Mark Sanderson, CESS, CT023, 2200 Lester Street, Quantico, VA 22134.

Point of Contact(s): Mark Sanderson 703-432-3271 email: mark.sanderson@usmc.mil

Contracting Office Address: M67854 MARINE CORPS SYSTEMS COMMAND Quantico, VA

Point of Contact(s): Mark Sanderson. Phone: 703-432-3271 Email: mark.sanderson@usmc.mil